



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GRAY DAVIS, GOVERNOR

Enforcement Team Meeting
March 21, 2000
Summary

9:00 a.m. – 3:45 p.m.

Present: Board Member Darlene Fujimoto
Board Member John Jones
Executive Staff
Supervising Inspectors
Inspectors
Enforcement Staff

Inspector Issues

As reported at the December team meeting, the inspector overtime claims are with the Department of Consumer Affairs for review. They anticipate that their review will be completed in approximately two months.

Supervising Inspector Robert Ratcliff reported that interviews with inspector applicants took place in February. The interview panel consisted of him and the inspector team leads. Each applicant was required to submit a writing sample, which is being reviewed. Once that is completed, tentative offers of employment will be made.

Ms Herold reported that the examination for Supervising Inspector will be scheduled either in April or May. She also announced that Mr. Castillo's limited-term position as supervising inspector ends in mid-April at which time he has elected to accept a position as inspector. However, he will continue to be assigned lead responsibilities by Supervising Inspector Robert Ratcliff.

Ms. Herold announced that Individual Development Plan (IDP) for employee reviews is anticipated during the next three months. Each staff will be sent an IDP form to complete and a job duty statement for revision if necessary. Then management will meet with each employee to discuss and finalized their plans and identify training needs for the next year.

Announcements/Introductions

Committee Chair Darlene Fujimoto called the meeting to order and asked team members to introduce themselves and their current position.

Quality Improvement Efforts

Committee Chair Darlene Fujimoto requested that the team take time to read the correspondence received from former Supervising Inspector Ken Sain regarding his perception of current board enforcement policies. She explained that President Richard Mazzoni received Mr. Sain's latest version and after reading it and consideration, President Mazzoni requested that the Enforcement Team evaluate the comments. Ms. Fujimoto requested discussion from team members on the various concerns that he raised. It was stated that the Enforcement Team is currently unable to evaluate if the inspector teams are working because of the inspector vacancies. However, it was noted that in order to evaluate "what is working", the team needs to define the measure of "what is working". It is evident that even with the inspector vacancies, inspector resources are focused on the high priority and more complex cases, which is reflected by the number of cases pending at the Attorney General's Office and the number of cases that each team is currently able to investigate and close.

The team agreed that the purpose of the "self evaluation" assessment form is to educate licensees on pharmacy law and what is expected during an inspection. It was never the board's intent to use the self-assessment in lieu of routine compliance inspections as alleged by Mr. Sain. However, due to inspector vacancies, the board has had to shift its resources to its investigation program, but there are plans to re-implement routine compliance inspections when the resources are available to do so. The Enforcement Team commented that its liaison efforts with other agencies were strong, critical and mutually beneficial. Again, because of limited resources, the board cannot always participate when requested because it must focus its resources on its own workload and priorities.

Overall, the team gave thoughtful consideration to Mr. Sain's comments and discussed the changes that have occurred over the last six years that have necessitated the board's strategic plan and the refocus of its resources. Many of the issues raised by Mr. Sain have been considered in previous team meetings. Some of the issues were concerning management decisions regarding procedures that have been implemented in order to ensure statewide consistency, efficiency and standardization, which is critical to any statewide enforcement program.

It was reiterated that many changes have occurred since Mr. Sain was an employee of the board, and the consensus of the Enforcement Team is that changes will occur and that they (the Enforcement Team) has dealt with them sufficiently and will continue to do so. The team expressed its preference not to review what was in the past and to move forward, update the strategic plan and continue its efforts to deal with changes in health care that affect the current practice of pharmacy.

Committee Chair Darlene Fujimoto reminded the Enforcement Team that the issues discussed during these team meetings are confidential and are not to be shared other than through the "official" meeting summary minutes provided at board meetings. It was apparent by Mr. Sain's letter that this policy has been compromised; thus reducing the trust among team members and

skewing the discussion of various enforcement issues that may hamper the board's public protection efforts and portray a negative image of the board.

The leads from the Compliance, Drug Diversion/Fraud, Pharmacist Recovery (PRP)/Probationer and Administrative teams reported on their activities for the Enforcement Team meeting. Each team provided information on their workload, significant accomplishments and presentations to outside organizations.

Some of the significant accomplishments reported were: completion of administrative cases, issuance of citation and fines, completion of two large audits, participation as an expert witness for another agency, participation at a binational conference on quality of Mexican prescription drugs, investigation of two high-profile patient confidentiality cases that had substantial media interest, revocation of a pharmacist's probation, near completion of procedure manuals for the Complaint Unit Team, completion of record retention for substantiated complaints, and compliance with the national HIPDB reporting requirements.

Committee Chair Darlene Fujimoto reported on the success of the CURES conference held February 4, 2000. She provided meeting summaries from the CURES workgroup on the evaluation of the CURES data. The Controlled Substance Prescription Abuse Prevention Task Force is scheduled to have its first meeting on July 12th, in Sacramento. The purpose of this task force is to assist the workgroup in establishing thresholds to review the Schedule II prescription data and identify practitioners for education or investigation.

Supervising Inspector Robert Ratcliff reported on status of completed cases since the last team meeting. He commended the inspectors and mediation analysts on their hard work and efforts to complete those cases over one year old. There are still some outstanding cases and he again directed that these cases be given priority for completion prior to the next meeting. The direction that inspectors must receive prior approval from their supervisor prior to a field visit to a pharmacy for investigation remains in effect.

He also provided an overview of the type of cases that will be assigned to the Complaint Mediation Team. With the implementation of this team to mediate the majority of the consumer complaints, the goal is for the Compliance Team to reinstate the routine compliance inspection program by July 2000. The parameters for this program will be drafted for discussion at the next team meeting. During strategic planning, the Enforcement Team will brainstorm the inspector focus during compliance inspections.

Proposed Cite and Fine Regulations

As one of its strategic objective, the Enforcement Team recommended and the board approved proposed amendments to its cite and fine program that would grant the board authority to cite and fine for any violation of pharmacy law. The draft regulations were provided for comment. An informational hearing is scheduled for the April board meeting.

Proposed Legislation for 2000

Ms. Herold reported on three bills that the board is sponsoring. SB 1339, which was a strategic objective of the Enforcement Committee, requires pharmacies to implement a quality assurance program to identify and prevent prescription errors and would exempt from discovery these programs. The second bill, AB 2018 would implement CURES permanently and eliminate the triplicate prescription requirement. The final bill is an omnibus bill that will contain non-controversial amendments to the pharmacy law such as the stocking of ambulances by pharmacies.

Strategic Planning for 2000/2001

The Enforcement Team brainstormed issues for board consideration during strategic planning. They were:

- development of compliance guidelines on enforcement issues for publication on board's website
- hospitals – recordkeeping and accountability, consolidation of services, contract of pharmacy services to off-site pharmacies, drug losses, supervision of technicians, distribution issues, satellites, use of automated devices
- obtain resources for proactive investigations and prosecution of internet pharmacies
- pharmacist-in-charge requirements
- enforcement of pharmacy services in correctional facilities
- worksite employment of pharmacists and technicians
- quarterly inspector meetings
- unlicensed activity
- discontinuance of business requirements for other licensed entities

Compliance Inspections

- consultation
- drug utilization review
- self-assessment form
- confidentiality – disposal of prescription records, refill requests, consultation
- pharmacist-in-charge
- prescription error accountability
- security
- sanitation
- ratios
- CURES compliance
- recordkeeping
- drug sourcing
- quality assurance program

- license status

Agenda Items for July Public Committee Meeting

The Enforcement Team brainstormed possible agenda items for the public meeting of the Enforcement Committee scheduled for July. The possible agenda items are:

- Confidentiality
- Complaint Process
- Compliance Inspection Focus
- Law Updates for Enforcement (what laws on the self-assessment form that are not working for pharmacy practice)
- Resources
- Website links – licensure verifications

Future Meetings

The next meeting of the Enforcement Team is June 20, 2000 and the team was informed to keep the 19th open as well because training on effective listening may be scheduled that day. The September meeting was rescheduled to the 14th.

Adjournment

The meeting was adjourned at 3:45 p.m.